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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellants: Solomon S. Steiner, Robert Feldstein, Per B. Fog, and Trent Poole

Serial No.: 09/621,092 Art Unit: 3743

Filed: July 21, 2000 Examiner: M. Patel

For: *UNIT DOSE CAPSULES AND DRY POWDER INHALER*

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**REPLY TO EXAMINER'S ANSWER**

Sir:

This is a Reply to the Examiner's Answer mailed October 6, 2005, in the above-referenced application. Submitted with this Reply Brief is a Third Substitute Appeal Brief that includes a "Related Proceedings Index", which was inadvertently omitted from the Appeal Brief filed on August 12, 2005, and specifically recites the claim number for the claims described in Section 5, "Summary of Claimed Subject Matter". Also submitted with this Reply Brief is a Request for Oral Hearing. The Commissioner is hereby authorized to charge \$500, the fee for a Request for Oral Hearing for a small entity, to Deposit Account No. 50-3129. It is believed that no additional fee is required with this submission. However, should an additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-3129.

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**(8) ARGUMENT**

Appellants affirm all of the arguments made in the Appeal Brief.

**(iii) Rejections Under 35 U.S.C. § 102**

Legal Standard: Claim Interpretation

The legal standard for determining the meaning of a term in a claim was recently set out in *Philips v. Awh Corp.*, 415 F.3d, 75 U.S.P.Q.2d 1321 (Fed. Cir 2005). *Phillips* stated that it is established case law that “the words of a claim ‘are generally given their ordinary and customary meaning.’” (*Philips*, 415 F.3d at 1312, citing *Vitronics Corp. v. Conceptor Inc.*, 90 F.3d 1576, 1582 (Fed. Cir 1996); *Toro C. v White Consol. Indus., Inc.*, 199 F.3d 1295, 1299 (Fed. Cir. 1999); *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1249 (Fed Cir. 1998). The “ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention.” *Philips*, 415 F.3d at 1313, citing *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004); *Ferguson Beauregard/Logic Controls v. Mega Sys., LLC*, 350 F.3d 1327, 1338 (Fed. Cir. 2003). The claims themselves provide substantial guidance regarding the meaning of particular claim terms. *Id.* at 1314. For example, the context in which a term is used can be very useful in determining the meaning of a term. *Philips* described how the term “steel baffles” “strongly implies that the term ‘baffles’ does not inherently mean objects of steel.” *Id.* Further, other claims in the patent should be reviewed to determine if they provide further insight into the meaning of a specific claim term. “For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not

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present in the independent claim.” *Id.* at 1315. The claims are not to be read in a vacuum, rather they must be read in the context of the specification. “As [the court] stated in *Vitronics*, the specification “is always highly dispositive; it is the single best guide to the meaning of a disputed term.” *Id.*, citing *Vitronics*, 90 F.3d at 1582. Thus a determination of the meaning of a claim term begins with a review of the claims and the specification.

Further, the court addressed the role of the use of dictionaries in determining the meaning of a claim term. It noted that the dictionaries may be helpful in determining the “true meaning of language in the patent claims.” *Id.* at 1318, citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995) (*en banc*), *aff’d*, 517 U.S. 370 (1996). However, in contrast to emphasizing the importance of the specification and claims, the court downplayed the role of extrinsic evidence, such as dictionaries, in determining the meaning of a claim term. The court explained that the problem of using dictionaries in claim construction is that they focus the inquiry on the abstract meaning of words rather than on the meaning of claim terms within the context of the patent. The court explained that “heavy reliance on the dictionary divorced from the intrinsic evidence risks transforming the meaning of the claim term to the artisan into the meaning of the term in the abstract, out of its particular context, which is the specification.” *Id.* at 1321. Thus, the Examiner should focus his review on the claims and the specification in his determination of the meaning of a claim term, and consider any extrinsic evidence through the lens created by the specification and the claims.

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Analysis

Claim 41

Claim 41, the sole independent claim in the pending application, defines a capsule. It appears that the Examiner is uncertain regarding the meaning of the term "capsule".

The specification as originally filed describes capsules. At page 9, lines 23-30, the specification explains that the capsule is designed to be used with an inhaler. At page 2, lines 10-12, the specification states that the mixing section of the inhaler holds a capsule containing a dry powder medicament. The medicament in the capsule is accessible when the apparatus is in a specific configuration. The capsule may be formed of two parts (page 2, lines 20-25). For the medicament to be stored in the capsule until administration, the capsule must be closed to the environment. One embodiment is illustrated in Figure 7. In this embodiment, the capsule is formed from two parts, where one part fits inside the other. These parts are described as two tubes, where each tube has a closed end and an open end (page 9, lines 25-27). When the two halves are put together, a capsule is formed which is closed at both ends. For the medicament to be released from the capsule, the one half is rotated so that two or more secondary holes align allowing air to flow through and release of the medicament contained inside the capsule (page 10, lines 10-14). Thus, contrary to the Examiner's assertion, the term "capsule" does not encompass elements in which one end is open and another end is closed. In fact, the specification uses a different term to refer to such elements; they are called "tubes" or "halves" (see e.g. page 2, lines 21 and page 9, lines 26-27).

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Instead of looking to the specification, as emphasized in *Philips*, the Examiner cited a dictionary definition from a general dictionary, Merriam Webster's Collegiate Dictionary, 10<sup>th</sup> Edition (see page 5 of the Examiner's Answer). A copy of the definition was not enclosed with the Examiner's Answer. However, assuming the Examiner's recitation of the definition is accurate, the cited definition also supports Appellants definition for the term "capsule." The Examiner quotes the dictionary as stating that a capsule is "a shell[,] usually of gelatin[,] for packaging something (as a drug or vitamins)", or "usually a medicinal or nutritional preparation for oral use consisting of the shell and its contents", or "a compact often sealed and detachable container or compartment". Contrary to the Examiner's assertion, each of these three definitions requires a container of some sort (e.g. a shell) that is capable of containing something (e.g. a medicament). To function in the required manner, the container has to be closed when it contains the medicament. Thus the extrinsic evidence provided by the Examiner viewed in context of the claims and the specification, does not support his interpretation of the definition for the term "capsule".

Similarly, the Examiner appears to be confused regarding the meaning of the term "distal end of the capsule", which identifies the location of the keying surface in claim 41. Claim 41 provides additional details regarding the location and function of the keying surface. It specifies that the keying surface is located on an *outside* surface of the capsule; and that the keying surface is adapted to (1) *orient* the capsule within the inhaler or (2) *identify* the drug to be placed in the capsule. The specification describes the location and function of the keying surface (see e.g.

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page 11, lines 14-16, 20-23, and 25-26; page 12, lines 8-15; and in Figures 7 and 18 (keying surfaces 430 and 360)). The specification explains that the keying surface is located on the closed end of the tube. Additionally, the specification describes the function of the keying surface. It explains that the keying surface allows for "easy tactile and visual identification of the orientation of the capsule." (page 11, line 18) In one embodiment, the keying surface is designed to mate with a keying surface on a second capsule, or a mechanical fastener in the storage section of the inhaler to allow for easy storage of the capsules (page 11, lines 21-23). In another embodiment, the keying surface is designed to mate with a holder in the mixing section of the inhaler (page 12, lines 8-9 and Figure 18). In another embodiment, the keying surface is located so that to allow for the identification of the drug, such as where each drug formulation in a capsule corresponds to a different inhaler, so that users cannot mix up drugs (page 11, lines 19-20) Thus, reading claim 41 in view of the specification, one of ordinary skill in the art would understand that the term "distal end of the capsule" indicates that the keying surface is located at an end of the capsule, not along the length of the entire capsule.

#### Claim 30

The Examiner alleges that the term "medicament", as used in claim 30, encompasses the tobacco products sold by R.J. Reynolds (and listed in col. 7, lines 49-60). This section of Keritsis clearly discusses the smoking articles that can be attached to the container for additive materials, not materials which are placed in the container. Further, the very suggestion that the inhalation of tobacco products is equivalent to delivering a medicine, i.e. an agent that promotes

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recovery from injury or ailment, is contrary to years of evidence, which show that these products often cause cancer. The other materials listed in Keritsis at col. 7, line 62 until col. 8, line 9 are disclosed to be used as additives that merely enhance flavor and taste of the smoking article.

Keritsis does not disclose or suggest that the additive container can be used to deliver medicaments, as required by claim 30.

**(9) SUMMARY AND CONCLUSION**

For the foregoing reasons and those presented in the Appeal Brief filed August 12, 2005, Appellants submit that claims 28-30, 41, and 43-45 are patentable.

Respectfully submitted,

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Date: December 6, 2005

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